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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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08/588,637 01/19/96 BARBOUR

A 454312-2420

020999  
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NEW YORK NY 10151

HM12/0221

EXAMINER

SWARTZ, R

ART UNIT

PAPER NUMBER

1645

20

DATE MAILED:

02/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/588,637

Applicant(s)  
Barbour et al

Examiner  
Rodney P. Swartz, Ph.D.

Group Art Unit  
1645



☒ Responsive to communication(s) filed on 28November2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-4, 6-10, 12, and 13 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 6-10, 12, and 13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

### DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (703)308-4244.
2. Applicants' Response to Office Action, received 28 November 2000, paper #18, is acknowledged.
3. Claims 1-4, 6-10, 12, and 13 are pending and currently under consideration.

### Rejection Maintained

4. The rejection of claims 1-4, 6-10, 12, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512, in view of Bergstrom et al (U.S. Pat. No. 5,523,089) or Cohen (*Immunization*, in, Basic & Clinical Immunology, 3rd ed., Fudenberg HH, Stites DP, Caldwell JL, Wells JV, eds., 1980) is maintained.

Applicants argue that the instant claims are directed to a method of inducing an immunological response by mucosally administering substantially pure OspA, while claim 2 of U.S. Pat. No. 5,688,512 is directed to a method of inducing a **protective** immunological response by administering substantially pure OspA (no particular route of administration is specified). Therefore, there is nothing in the disclosure of claim 2 of U.S. Pat. No. 5,688,512 that teaches or suggest **the particular mucosal administration** of substantially pure OspA to produce the **generalized** immunological response of the instant claims.

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The examiner has considered applicants' argument, but does not find it persuasive for reasons of record. The instant claims are directed to a method of inducing an immunological response (of which a protective response is just such an immunological response) in a mammalian host (animals and humans being mammals) comprising administration (which encompasses mucosal, intradermal, intravenous, etc) of a composition comprising substantially pure OspA and a carrier or diluent.

#### **Conclusion**

5. Claims 1-4, 6-10, 12, and 13 remain rejected.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

Art Unit 1645

February 19, 2001